



### CLAIMS LISTING

1. **(Cancelled):** A dosage form comprising anhydrous mirtazapine or its pharmaceutically acceptable salts.
2. **(Withdrawn):** The dosage form as claimed in claim 1, wherein the dosage form comprises film-coated tablets of anhydrous mirtazapine or its pharmaceutically acceptable salts, low-substituted hydroxypropylcellulose and one or more pharmaceutically acceptable excipients.
3. **(Cancelled):** The dosage form as claimed in claim 1, wherein the dosage form comprises orally disintegrable tablets of anhydrous mirtazapine or its pharmaceutically acceptable salts, and one or more non-effervescent excipients.
4. **(Withdrawn):** The dosage form as claimed in claim 2, wherein the particle size distribution of anhydrous mirtazapine or its pharmaceutically acceptable salt used in the tablet is such that the diameter of 90% of the particles is less than 600  $\mu\text{m}$ , more preferably less than 400  $\mu\text{m}$ .
5. **(Cancelled):** The dosage form as claimed in claim 3, wherein the particle size distribution of anhydrous mirtazapine or its pharmaceutically acceptable salt used in the tablet is such that the diameter of 90% of the particles is less than 600  $\mu\text{m}$ , more preferably less than 400  $\mu\text{m}$ .
6. **(Withdrawn):** A process for the preparation of film-coated tablets of mirtazapine, comprising anhydrous mirtazapine or its pharmaceutically acceptable salts, low substituted hydroxypropylcellulose and one or more pharmaceutically acceptable excipients.
7. **(Withdrawn):** A process for the preparation of hard, compressed, orally disintegrable tablet dosage form of mirtazapine comprising anhydrous mirtazapine or its pharmaceutically acceptable salts, and one or more non-effervescent excipients.
8. **(Cancelled):** The dosage form as claimed in claim 3, wherein the said non-effervescent excipients comprise binders, diluents, dispersing agents, flavoring agents, sweetening agents, lubricants, glidants.
9. **(Cancelled):** The dosage form as claimed in claim 3, further comprises anhydrous mirtazapine or its pharmaceutically acceptable salt from about 1 to 50% by weight of the tablet.

10. **(Cancelled):** The dosage form as claimed in claim 8, wherein the dispersing agent is selected from the group consisting of crosscarmellose sodium, crosspovidone, sodium starch glycolate, sodium carboxymethyl cellulose, hydroxypropyl cellulose, xanthan gum, alginic acid, alginates and carbopols and combination thereof.

11. **(Cancelled):** The dosage form as claimed in claim 8, wherein the diluent is selected from the group consisting of calcium phosphate-dibasic, cellulose-microcrystalline, cellulose powdered, calcium silicate, polyols such as mannitol, sorbitol, xylitol, maltitol, sucrose, lactose and combinations thereof.

12. **(Cancelled):** The dosage form as claimed in claim 8, where the binder is selected from the group consisting of methylcellulose, hydroxypropyl cellulose, hydroxypropyl methylcellulose, polyvinylpyrrolidone, gelatin, gum Arabic, ethyl cellulose, polyvinyl alcohol, pullulan, starch, pregelatinized starch, agar, tragacanth, sodium alginate, propylene glycol, alginate, plasdone and combinations thereof.

13. **(Cancelled):** The dosage form as claimed in claim 8, wherein the lubricant is selected from the group consisting of talc, magnesium stearate, stearic acid, glyceryl behenate and mixtures thereof and glidants is selected from the group consisting of colloidal silicon dioxide, talc and mixtures thereof.

14. **(Cancelled):** The dosage form as claimed in claim 8, wherein the sweetener is selected from the group consisting of sugars, sucrose, lactose, glucose, saccharin, saccharin salts, mannitol, aspartame and combinations thereof.

15. **(Cancelled):** The dosage form as claimed in claim 8, wherein the flavoring agent is selected from the group consisting of strawberry guarana, peppermint, cherry, mint, caramel, raspberry, lemon, orange, tutti-fruity, banana, bubble gum, preferably strawberry, guarana, peppermint flavor or combination thereof.

16. **(Withdrawn):** The dosage form as claimed in claim 2, wherein the pharmaceutically acceptable excipients comprise binders, diluents, dispersing agents, lubricants and glidants.

17. **(Withdrawn):** The dosage form as claimed in claim 16, wherein the dispersing agent is selected from the group consisting of crosscarmellose sodium, crosspovidone, sodium starch glycolate, sodium carboxymethyl cellulose, hydroxypropyl cellulose, xanthan gum, alginic acid, alginates, and carbopols and mixtures thereof.

18. **(Withdrawn):** The dosage form as claimed in claim 16, wherein the diluent is selected from the group consisting of calcium phosphate-dibasic, cellulose-microcrystalline, cellulose powdered, calcium silicate, polyols, mannitol, sorbitol, xylitol, maltitol, sucrose and combinations thereof.

19. **(Withdrawn):** The dosage form as claimed in claim 16, wherein the binder is selected from the group consisting of methylcellulose, hydroxypropyl cellulose, hydroxypropyl methylcellulose, polyvinylpyrrolidone, gelatin, gum arabic, ethyl cellulose, polyvinyl alcohol, pullulan, starch, pregelatinized starch, agar, tragacanth, sodium alginate, propylene glycol, alginate, plasdone and mixtures thereof.

20. **(Cancelled):**

21. **(Cancelled):**

22. **(Withdrawn):** A process for the preparation of film coated tablets of anhydrous mirtazapine or its pharmaceutically acceptable salts comprising the steps of: i) blending anhydrous mirtazapine with disintegrants, diluents and/or binders ii) milling and granulating the blend with purified water to obtain granules, iii) drying the said granules and mixing the dried granules with diluents and lubricants, iv) compressing the granule mixture into tablets, v) coating the tablets.

23. **(Withdrawn):** A process for the preparation of orally disintegrating tablets of anhydrous mirtazapine or its pharmaceutically acceptable salts comprising the steps of: i) blending anhydrous mirtazapine with disintegrants, diluents and/or binders, ii) milling and granulating the blend with a solvent to obtain granules, iii) drying the said granules and mixing the dried granules with diluents, lubricants, flavoring agents, sweetening agents, iv) compressing the granule mixture into tablets.

24. **(New):** A hard, compressed, orally disintegrable tablet dosage form comprising about 1 to 50%w/w of anhydrous mirtazapine or its pharmaceutically acceptable salts and a mixture of non-effervescent excipients comprising about 10% to 80%w/w of diluents, 2% to 15%w/w of at least one dispersing agent.

25. **(New):** The dosage form as claimed in claim 24, wherein the particle size distribution of anhydrous mirtazapine or its pharmaceutically acceptable salt used in the tablet is such that the diameter of 90% of the particles is less than 400  $\mu\text{m}$ .

26. **(New):** The dosage form as claimed in claim 24, wherein the diluent is selected from the group consisting of calcium phosphate-dibasic, cellulose-microcrystalline, cellulose powdered, calcium silicate, polyol such as mannitol, sorbitol, xylitol, maltitol, sucrose, lactose and combination thereof.

27. **(New):** The dosage form as claimed in claim 24, wherein the dispersing agent is selected from the group consisting of crosscarmellose sodium, crosspovidone, sodium starch glycolate, hydroxypropyl cellulose and combination thereof.

28. **(New):** The dosage form as claimed in claim 24, wherein the non-effervescent excipients further comprise lubricants, sweeteners and flavoring agents.

29. **(New):** The dosage form as claimed in claim 28, wherein the lubricant is selected from the group consisting of talc, magnesium stearate, stearic acid, glyceryl behenate and mixtures thereof and glidants is selected from the group consisting of colloidal silicon dioxide, talc and mixtures thereof.

30. **(New):** The dosage form as claimed in claim 28, wherein the sweetener is selected from the group consisting of sugars, sucrose, lactose, glucose, saccharin, saccharin salts, mannitol, aspartame and combinations thereof.

31. **(New):** The dosage form as claimed in claim 28, wherein the flavoring agent is selected from the group consisting of strawberry guarana, peppermint, cherry, mint, caramel, raspberry, lemon, orange, tutti-fruity, banana, bubble gum, preferably strawberry, guarana, peppermint flavor or combination thereof.